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'Risky Strategy': CDC Signs Off on Pfizer RSV Vaccine for Pregnant Women to Protect Newborns

Cardiologist Peter McCullough, M.D., MPH, told The Defender, "Vaccination of the mother for passive immunization of the infant is an unnecessary and risky strategy that will undoubtedly lead to fetal loss or premature deliveries when deployed on a large scale."

By **Michael Nevradakis, Ph.D.**

15

RSV
RESPIRATORY SYNCYTIAL VIRUS
VACCINE
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An advisory committee to the Centers for Disease Control and Prevention (CDC) last week recommended a new vaccine for respiratory syncytial virus (RSV) — the first such vaccine for pregnant women designed to target newborns, NBC News reported.

In an 11-1 vote on Friday, the Advisory Committee on Immunization Practices (ACIP) endorsed Pfizer's Abrysvo. The vote was followed by a formal recommendation by CDC Director Mandy Cohen, completing the final regulatory step before distribution of the vaccine to the public can begin.

Cohen praised the new vaccine, calling it "another new tool we can use this fall and winter to help protect lives." Cohen encouraged parents to talk to their doctors about "how to protect their little ones against serious RSV illness."

But doctors who spoke to The Defender took a different view. Cardiologist Peter McCullough, M.D., MPH, said:

> "Vaccination of the mother for passive immunization of the infant is an unnecessary and risky strategy that will undoubtedly lead to fetal loss or premature deliveries when deployed on a large scale.
>
> "As a clinician, my greatest concern with any vaccination in pregnancy is provocation of fever, which is one of the most common determinants of preterm labor and in some cases fetal loss or premature delivery."

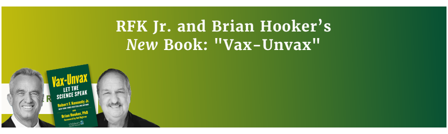
The CDC's formal approval of Abrysvo comes just weeks after the U.S. Food and Drug Administration (FDA) approved the vaccine.

Abrysvo will be administered to pregnant women during the third trimester of pregnancy, Reuters reported. According to ACIP members, vaccination late in pregnancy "is likely to reduce a possible risk of preterm births and complications that might arise from taking it earlier."

According to NBC News, "The single-dose shot … spurs the production of antibodies in the mother that transfer through the placenta." Referencing clinical trial data published in the New England Journal of Medicine (NEJM), NBC News said Abrysvo's "protection lasts through their first six months."

According to Reuters, ACIP member Dr. Katherine Poehling, a professor of pediatrics and epidemiology and prevention at Wake Forest University School of Medicine, said, "RSV throughout my career has been a difficult disease with just supportive care treatment because there have been no options so today is an exciting day."

STAT News quoted Luis Jodar, Pfizer's chief medical affairs officer for vaccines/antivirals and evidence generation, who said, "Today's ACIP recommendation for maternal immunization with Abrysvo reinforces the wide-ranging impact vaccines can have, including helping protect infants immediately at birth from the potentially severe and life-threatening complications that can develop from RSV."



RSV vaccination for pregnant women 'unnecessary and risky'

In an appearance on CHD.TV earlier this month, Dr. Meryl Nass, an internist and member of the Children's Health Defense (CHD) scientific advisory committee, said that during clinical trials, Abrysvo "caused more preterm deliveries and low birth weight babies," and, she said, "there was no risk benefit analysis performed."

"GSK dropped their vaccine candidate that was almost identical," due to such concerns, Nass added.

An FDA briefing document stated safety data from Abrysvo clinical trials was "generally favorable." Data published in the NEJM indicated that, when administered at 32 to 36 weeks gestation, Abrysvo reduced the risk of severe disease by 91% in the first three months of life, and 77% in the first six months.

However, NBC News previously reported that after six months, Abrysvo "didn't appear to make a big difference," and noted that a "slightly higher rate of preterm births — defined as before 37 weeks gestation — among people who received the vaccine (5.7%) versus those who got a placebo (4.7%)" was identified.

"The difference wasn't statistically significant, however, so it's unclear whether it was vaccine-related," NBC News added. CNBC reported that both percentages were below the overall percentage for preterm births in the general population (10%).

Yet, according to CNBC, the clinical trial for Abrysvo "reported 18 peripartum fetal deaths." The FDA stated that these deaths were "unlikely" to be related to the shot.

Axios reported that "The fetal deaths present in the vaccine group (0.3%) were not related to Pfizer's vaccine … Similarly, 4 out of 5 infant deaths were considered unrelated to the shot, with one being possibly connected to the shot, although that remains unclear."

Clinical trial data reported by Pfizer to the CDC indicated that 14% of pregnant women who participated in Pfizer's trial sustained an adverse event, with 4.2% sustaining a "serious" adverse event, 1.7% experiencing a "severe" adverse event and 0.5% suffering a "life-threatening" adverse event.

The same data showed that 37.1% of infants whose mothers received the experimental Pfizer vaccine experienced adverse events within one month of birth — with 15.5% classified as "serious," 4.5% as "severe" and 1% as "life-threatening."

NBC News reported that the most common side effects reported by pregnant women were fatigue, headache, muscle pain and injection site pain.

According to attorney, journalist and podcaster Daniel Horowitz, Phase 2 trial data for Abrysvo showed that "Pfizer reported 3 out of 116 (2.6%) premature births in the placebo group and 6 out of 114 (5.3%) in the group that received the vaccine that was chosen as Pfizer's final product."

According to the National Vaccine Information Center, "The RSV clinical trial data also included the death of one pregnant woman, 18 stillbirths (10 in vaccinated pregnant women and eight in unvaccinated pregnant women), and 17 infant deaths (five from the vaccinated pregnancy group and 12 in unvaccinated pregnancy group)."

RSV in babies 'common and easily treated'

Experts also questioned the need for an RSV vaccine for newborns and infants.

According to STAT, "Until this year, there have been no tools with which to prevent RSV," adding that it causes "enormous numbers of illnesses in young babies every year."

However, STAT conceded that "the death toll in this country" among infants "is not high," but noted that "1.5 million children are taken for medical care for RSV every year, nearly half a million end up in an emergency room, and between 58,000 and 80,000 are hospitalized for these infections," citing CDC figures.

NBC News, citing the same CDC data, said that RSV causes "up to 300 deaths annually" among children 5 and younger. "Last year, a dramatic spike in severe RSV infections overwhelmed children's hospitals."

However, NBC News conceded that "RSV is also common — most children are infected in the first year of life, and almost all by age 2."

According to McCullough, RSV among infants under age 1 is common and easily treated with nebulizer therapy either at home or in the clinic. "Hospitalization is usually a product of inadequate home treatment and supportive care in the hospital is usually brief," he said.

And Nass, speaking to CHD.TV, said RSV "generally causes colds," but that "this particular virus in very young infants may often cause them to have difficulty breathing." That can lead to hospitalization and the need for "supportive care."

However, she said that "by the age of 2, 97% of all babies have been infected with an RSV virus and get a partial immunity, so the next episode is not going to be as severe as the first one. You never get full immunity from cold viruses. As you know, we keep getting colds throughout our lives."

Nass said that RSV death figures among babies are being misrepresented.

"Four million babies, 26 death certificates per year that say RSV, of which 17 death certificates actually blame RSV for the death as the underlying cause of death," Nass said. "Seventeen babies under the age of 1 who die per year, and this is from a CDC study."

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According to Nass, the CDC study spanned 12 years, during which "There were only 1,001 death certificates that listed RSV on them in the entire United States. So that's less than 100 people dying with an RSV-associated death per year. And of them, only 17 babies per year are thought to be due to RSV."

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'Mothers should decline this vaccine'

In August, the CDC approved Beyfortus, an injectable monoclonal antibody targeting RSV. The drug also is intended for newborns and infants up to 8 months old born during or entering RSV season, and for infants 8-19 months who are at "increased risk of severe disease and entering their second season," according to NBC News.

The FDA approved Beyfortus in June. Similarly, ACIP approved Abrysvo for administration during peak RSV season, between September and January, in what STAT described as a "limited recommendation" for the vaccine from ACIP, and "not a clear victory" for Pfizer. This is because ACIP's approval "limit[s] the time of the year" during which Abrysvo can be administered.

"The Pfizer vaccine would not be recommended for use in most of the continental U.S. from February to August," with certain exceptions in regions where "RSV can circulate year-round," such as Alaska, parts of Florida, Hawaii, Puerto Rico, Guam and the U.S. Virgin Islands. There, Abrysvo's seasonal availability would not be applicable.

Earlier this month, the CDC warned there were "increases" in RSV cases in "some parts of the Southeastern United States."

The one dissenting member of ACIP, in its 11-1 vote to recommend Abrysvo, questioned the need for the vaccine on the basis that Beyfortus is already available.

"What's the benefit of this vaccine? Why recommend it at all?" Helen Keipp Talbot, M.D., MPH, a Vanderbilt University professor medicine and associate professor of pediatrics, asked, in remarks published by STAT.

However, according to STAT, the approval of Abrysvo and Beyfortus by the CDC and FDA "was an attempt to make the choice of preventive measures less complicated" for parents. "The goal is to ensure babies are protected with one or the other anti-RSV product, but ideally not both together."

According to NBC News, ACIP said either shot can be used to protect infants, and most babies won't need both. "CDC advisers also noted that the availability of Beyfortus may be limited during the current RSV season."

"The benefits of the vaccine are that it protects babies immediately after birth and doesn't require them to get a shot. However, the antibody injection doesn't pose a risk of adverse pregnancy outcomes, and some evidence suggests its protection wanes more slowly," NBC News added.

Yet, 12 deaths occurred during clinical trials for Beyfortus.

STAT reported that ACIP's recommendation for the administration of Abrysvo during the September-January period is not mutually exclusive with the administration of Beyfortus. Expectant mothers will have the option of receiving Abrysvo during pregnancy or their baby receiving the monoclonal antibody after birth.

A CDC data modeling forecast released last week predicted this year's RSV season will be similar to last year's and will peak alongside COVID-19 and influenza. Total hospitalizations from the three are also expected to be similar to last year's levels.

According to Forbes, Pfizer presented data to the FDA claiming Abrysvo will prevent 16,000 hospitalizations if made available this fall.

Yet, for McCullough, there is little cause for concern for most parents.

"With anticipated partial protection in babies against a mild illness, mothers should decline this vaccine and let the pregnancy progress as naturally as possible in the final trimester," he said.

Watch the ACIP meeting:

ACIP MEETING
MATERNAL RSV VACCINE SAFETY
September 22, 2023 at 10am - 4pm ET
Liveblog by Meryl Nass, M.D.
WATCH ON CHD.TV
CDC

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Michael Nevradakis, Ph.D.

Michael Nevradakis, Ph.D., based in Athens, Greece, is a senior reporter for The Defender and part of the rotation of hosts for CHD.TV's "Good Morning CHD."

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Best Newest Oldest

nick quinlan
3 days ago

Never vaccinate anyone you love, with anything.
Especially pregnant women.
The entire vaccine industry is nothing but organized crime, masquerading as health care.

24 0 Reply • Share ›

Bry
3 days ago

CDC rubberstampers approve anything that comes down the pike since they have no liability

19 0 Reply • Share ›

tbran10
3 days ago

My professional opinion is that the risk of RSV is superseded by the risk of adverse effects from the injection, administered to millions of pregnant women!

17 0 Reply • Share ›

Ricky Ricardo
3 days ago

All of this "Safe and Effective", "Protects you and others", "Protects your newborn"...tells me that the LAWS no longer have any meaning. Just like Satan, these demons come only to **Kill, Steal and Destroy** - and they get away with it!
We're the CDC and we approve genocide!

15 0 Reply • Share ›

BChristine
3 days ago

CRIMINAL beyond words.

15 0 Reply • Share ›

ralphdevane@msn.com
3 days ago

How can anyone give the CDC any credibility after Dr. Birx torched them after one of the WH Covid Panel meetings by saying "I can no longer trust anything coming out of the CDC"?

8 0 Reply • Share ›

> **Kim from Brooklyn** → ralphdevane@msn.com
> 2 days ago
>
> That, ralphd, is why the hole keeps getting deeper and darker by the minute.
>
> 3 0 Reply • Share ›

Jerry Alatalo
2 days ago

The shocking and disturbing discussion between Dr. James Thorp and Naomi Wolf is arguably the most important of the COVID era regarding the unwise vaccination of pregnant women.

Apparently new CDC Director Mandy Cohen hasn't received Dr. Thorp and Ms. Wolf's unforgettable, urgent message.

https://naomiwolf.substack....

7 0 Reply • Share ›

Clare Goldsberry
2 days ago

This is just another part of the "plan" -- I think a lot of women have learned their lesson about "vaccines" and why they are dangerous for pregnant women. Back in the day when I was pregnant, we weren't even supposed to drink coffee or take an aspirin!! Alcohol? NO! Now, it's anything goes! All is "safe and effective."
INSANITY!

6 0 Reply • Share ›

> **Kim from Brooklyn** → Clare Goldsberry
> a day ago
>
> The world has certainly changed, hasn't it?

0 0 Reply • Share ›

Jennifo

2 days ago

Insanity. Stupid mothers! Drinking alcohol while pregnant is considered criminal but hey let's inject mystery toxins in us while growing a human...great idea.

These mothers are idiots. And I can say that as a mother of 5. I carefully considered even 1 motrin while pregnant.

They will genuinely be surprised at the results too.

6 0 Reply • Share ›

Kim from Brooklyn ➜ Jennifo

a day ago

Thank you for being such a great mom! :) Keep it up. !

0 0 Reply • Share ›

Kim from Brooklyn

2 days ago

Obviously, some are just hypnotized and mentally controlled. Not to mention as long as they keep getting $$ then everything checks out for them. Although the sides seem very unbalanced, the longer we maintain momentum, there is hope.

5 0 Reply • Share ›

jerry

2 days ago

Decline, ladies.

4 0 Reply • Share ›

Kim from Brooklyn

a day ago

Repeat after me: No thank you.

0 0 Reply • Share ›

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